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(54) Apparatus and process for application and adjustable reprofiling of synthetic lenticles for vision correction.

(57) An apparatus and process for applying a synthetic lenticule (40) to the cornea (30) of a human eye is disclosed, the process also contemplating selective reprofiling of the lenticule while it is in place over the cornea. The process involves ablating a shallow peripheral groove (54) in the cornea to receive the peripheral edge of the lenticule which is then secured therein with an adhesive, thus leaving the visual axis of the eye undisturbed. The lenticule is placed over the cornea with a unique micro-manipulation apparatus (58) and normally under vacuum conditions. A laser delivery system is used to reprofile the lenticule if necessary for refining the refractive power of the lenticule.

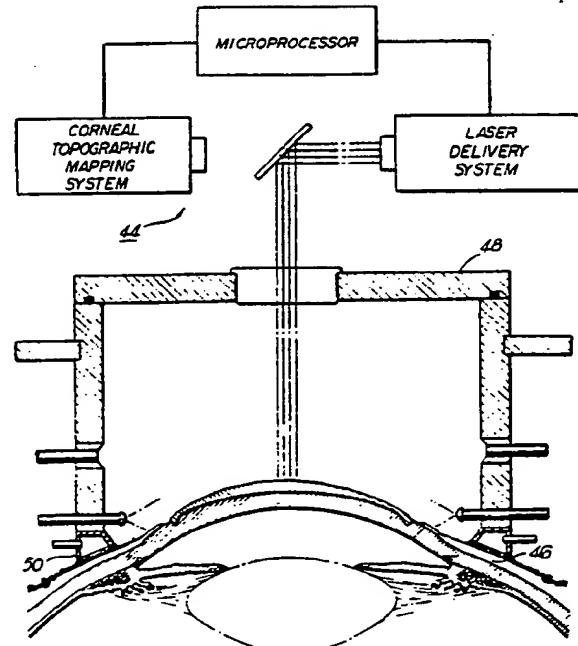


FIG 5

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APPARATUS AND PROCESS FOR APPLICATION AND ADJUSTABLE REPROFILING OF SYNTHETIC LENTICULES FOR VISION CORRECTION

BACKGROUND OF THE INVENTION

Thirty to forty percent of the human population develop an ocular refractive error requiring correction by glasses, contact lens, or surgical means. Refractive errors result when the optical elements of the eye, the cornea and the lens, fail to image light directly on the retina. If the image is focused in front of the retina, myopia (nearsightedness) exists. An eye which focuses images behind the retina is said to hyperopic (farsighted). An eye which has power that varies significantly in different meridians is said to be astigmatic. The focusing power of the eye is measured in units called diopters. The cornea is responsible for about two-thirds of the eye's 60 diopter refracting power. The crystalline lens contributes the remainder.

The search to find a permanent cure of refractive errors, including myopia, hyperopic, or astigmatism has gone on for many years. An effective, safe, predictable, and stable correction for these ametropias would have enormous social and economic impact.

Ophthalmologists have derived a number of surgical procedures which attempt to correct refractive errors. None of these techniques have gained widespread acceptance because the procedures generally have unpredictable outcomes and undesirable side effects such as glare, fluctuating vision, and corneal scarring. Unpredictable refractive outcome is the primary reason radial keratotomy has not been accepted by a majority of ophthalmologists as an effective treatment for myopia. Two other recent techniques to correct ametropias are briefly described below.

Epikeratophakia (meaning lens on top of the cornea) is a technique in which a donor cornea, termed a button, is used to make a lens which is sewn or glued to the surface of the patient's cornea in an attempt to correct his refractive error. This procedure involves freezing the donor corneal tissue and grinding the posterior surface to the desired optical configuration. This donor lenticule is then usually sewn into a groove in the patient's cornea cut by a circular mechanical trephine. Epikeratophakia is used primarily in patients who have had cataract operations and in whom an intraocular lens is contraindicated, such as children or older patients with certain eye diseases, and has also been used to correct for myopia.

There are several problems with epikeratophakia which render its routine use for patients with refractive errors unsatisfactory. The pro-

cedure is highly unpredictable and errors in refraction exceeding thirty percent of the expected change are common. Decrease in the patient's best correctable visual acuity is also encountered following epikeratophakia.

The refractive change achieved by epikeratophakia is not adjustable, and patients who are grossly over or under corrected must have the button removed and replaced.

A second technique to correct refractive errors, termed photorefractive keratectomy, has recently been developed. Energy generated by a pulsed argon fluoride excimer laser at a wavelength of 193 nm causes a precise removal of corneal tissue without adjacent thermal or mechanical damage. Several optical laser delivery systems have been described which attempt to achieve a controlled etching of the anterior cornea to the desired refractive curvature. Unfortunately, three major shortcomings render this technique clinically unacceptable for some patients: scarring, unpredictable outcome, and refractive instability.

Since this procedure is performed directly in the visual axis, any scarring is unacceptable. Several investigators have demonstrated relatively dense opacification of the cornea in animals following a reprofiling procedure with the 193 nm excimer laser. Although the scarring may be reduced by improvements in the optics of the delivery systems, there will remain very significant risks associated with irreversible treatment of the central optical axis of the eye.

A second problem with photorefractive keratectomy is the unpredictable refractive outcome of the technique. The final curvature of the ablated cornea will be influenced by stress and strain distribution changes occurring following ablation. Since the eye is a pressurized sphere, removal of some of its anterior surface causes the remaining tissue to accept a higher load of wall tension caused by the intraocular pressure. The net effect of this redistribution will cause the ablated cornea to shift in an anterior direction following photorefractive keratectomy, inducing a steepening of the optical zone. The extent of this shift will vary with the intraocular pressure, the patient's age, and tissue characteristics and therefore can cause significant variations in optical outcome.

Another serious problem with directly reprofiling the central area of the anterior corneal surface is the inability of the procedure to achieve a stable outcome. The majority of the thickness of the cornea is termed the stroma and consists of water, collagen fibers, a matrix substance, and numerous

cells called keratocytes. The keratocytes, which reside between Bowman's layer and Descemet's membrane, help produce and maintain the collagen structure of the corneal stroma. These cells are also responsible for wound healing following corneal injury. When Bowman's layer is violated, these cells produce new collagen and attempt to reform the injured or disrupted fibers. The cornea heals in a very slow fashion with the keratocytes laying down and remodeling new collagen over many months to years.

During photorefractive keratectomy, a certain depth of the anterior cornea is ablated, depending on the refractive change desired. The more refractive change needed, the deeper the required ablation. Despite the fact that the collagenous surface re-epithelializes normally after laser ablation, the keratocytes begin to produce new collagen in an attempt to restore the thinned stroma. This regeneration of new collagen (which is highly variable) in the anterior stroma will cause the corneal curvature to continually change as new collagen is added.

In addition to stroma collagen regeneration, investigators have noted a compensatory thickening of the epithelium following photoablative keratectomy. This hyperplastic epithelium, which may result from wound healing mediators, will vary in its thickness over time and contribute to the instability or the refractive outcome. Since the processes of stromal collagen regeneration and epithelial hyperplasia occur over a long period of time, the refractive power of the eye will be constantly fluctuating for many months or years following the procedure.

SUMMARY OF THE INVENTION

It is, therefore one of the principal objects of the present invention to provide an apparatus and process for application of a synthetic lenticule for effecting corrections in visual acuity obviating the need for glasses and/or contact lenses, the process including steps for safely and easily reprofiling the lenticule after application without its removal should future corrections be necessary.

Another object of the present invention is to provide a process for application of a synthetic lenticule which does not require ablation of the central corneal region or Bowman's layer, thereby avoiding disturbance of the visual axis of the patient, utilizing instead a minimal shallow ablation of the optically insignificant peripheral corneal region.

A further object of the present invention is to provide an apparatus and a process in which the synthetic lenticule can be safely and easily removed and replaced with a different synthetic len-

ticule if necessitated by the physical condition of the patient or by other factors.

A still further object of the present invention is to provide a process which corrects refractive errors in patients and which avoids the previously mentioned problems associated with current techniques and procedures.

These and additional objects are attained by the present invention which relates to an apparatus and a process for application and reprofiling, if necessary, a synthetic lenticule for vision correction. The process involves the steps forming a shallow, peripheral groove in the cornea following removal of the overlying epithelium. A synthetic lenticule, which has been formed to correct the particular refractive error in the patient's vision, is then secured in the peripheral groove and over the undisturbed central corneal region utilizing the present apparatus. The application of the lenticule is normally carried out under vacuum conditions and certain pharmacological agents may then be applied to the surface of the lenticule to enhance the regrowth of the normal epithelial cells over the lenticule. A further step includes selective reprofiling of the lenticule by laser ablation for refining the refractive power of the lenticule.

The process thus provides a safe and effective means for correcting visual acuity without the central surgical invasion of the cornea attendant in certain prior art techniques. Adjustment or fine tuning of the visual correction imparted is quickly and easily performed in a matter of minutes if needed after application of the lenticule.

Various additional objects and advantages of the present invention will become apparent from the following description, with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a partial, side elevational and cross-sectional view of the outer half of a normal human eye.

Figure 2 is an enlarged; partial cross-sectional view of the outer half of the eye, shown prior to the operation embodying the present process;

Figure 3 is an enlarged, partial cross-sectional view, similar to the preceding figure, with the epithelium removed, exposing the anterior surface layer of the cornea;

Figure 4 is an enlarged, partial cross-sectional view, similar to the preceding figure, shown with the outer peripheral groove formed in the cornea;

Figure 5 is a diagrammatical view of a laser apparatus suitable for ablating the peripheral groove and for reprofiling the lenticule.

Figure 6 is a partial top plan view of the eye, corresponding to the view shown in Figure 4;

Figure 7 is an enlarged, partial, cross-sectional view showing a sealant means disposed in the groove for receiving the edge of the lenticule, the view being taken on line 6-6 of Figure 5;

Figure 8 is a diagrammatical view, shown partially in cross-section, of the apparatus used for placing the lenticule over the cornea;

Figure 9 is an enlarged partial, cross-sectional view, similar to Figure 4, showing the lenticule secured in place over the cornea;

Figure 10 is an enlarged, partial, cross-sectional view, similar to the preceding figure, schematically illustrating reprofiling of the lenticule; and

Figure 11 is an enlarged, partial cross-sectional view, similar to the preceding figure, showing the reprofiled lenticule in place with the epithelium regrown thereover.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now more specifically to the drawings, and to Figure 1 in particular, numeral 20 designates generally the outer half of the human eye upon which the present process for vision correction is performed, portions thereof being described hereinbelow as an aid in understanding the present process. The portions of the cornea 21 of the eye which are involved in the present process include an outer layer of epithelial cells 22 which cover the outer cornea, which is known as Bowman's layer 24. The cornea has an inner corneal membrane 26, known as Descemet's membrane, which has a covering layer 28 on its posterior surface, termed the endothelium. Between the anterior and posterior boundaries are layers of striated tissue, termed the stroma 30, which comprise the bulk of the cornea 21.

The visual axis of the eye, one point of which is indicated generally at 32, can be considered as an imaginary line which extends through the central region, including the cornea 21, the lens 34, and the vitreous region 36 to the rear of the eyeball near the optic nerve (not shown). This central region of the cornea is the most important region of the cornea with regard to the vision of the patient. This factor, which has been observed in the outcomes of several of the prior art techniques previously described, is a major reason why the present process specifically avoids any surgical invasion of the central region of the cornea.

Figure 2 illustrates in magnified detail the section of the eye shown in Figure 1, shown prior to beginning the process embodying the present invention. Before any corrective measures are undertaken, a detailed analytical profile of the patient's cornea is made and analyzed by the physician. Such a profile may be obtained from a corneal topographic mapping system such as, for example, the Corneal Modeling System developed by the Computed Anatomy Corp. of New York, New York. Such computer modeling provides the physician with a three dimensional profile of the cornea and precisely defines its anterior shape. Thus, patients with refractive errors would undergo ocular examinations to obtain data used in determining the lenticule manufacturing criteria. Corneal topographic data is used to determine the posterior shape of the lenticule, and refractive data is used to determine the anterior shape. The lenticule can then be manufactured to meet individual patient specifications.

Armed with this data, the physician designs and orders an appropriate lenticule having the desired refractive characteristics. The lenticule is manufactured from a synthetic or reconstituted polymer, such as a preferred synthetic collagenous polymer, or other suitable synthetic material that is biocompatible with the tissues of the eye. The lenticule is prepared and treated with appropriate chemical means to achieve the desired properties of constituency, optical clarity and stability. The material also has characteristics such that it is resistant to invasion and/or degradation by cells and cellular agents. The material can be shaped to the desired specifications by injection molding, lathe cutting, laser profiling, or a combination of these and/or other techniques. Additionally, the material used for the lenticule has the capability to support and maintain epithelial growth in a normal fashion over its anterior surface and has transparent optical characteristics for light in the visible spectrum. A final requirement of the synthetic material is that it will allow laser reprofiling of its anterior surface after attachment to the cornea, which is a significant and unique step disclosed by the present inventive process. Such materials meeting the above requirements are currently available on the market and other suitable synthetic materials are likely to be developed. It is important to note however, that the present process does not involve or contemplate the use of donor corneal material from a human eye.

With the detailed profile of the anterior surface of the cornea, that is, Bowman's layer 24, provided by a suitable mapping system, the posterior surface 38 of the lenticule 40 (Figure 8) is configured such that it precisely matches the patient's anterior corneal curvature after the removal of the epithel-

lum 22. The anterior surface 42 of the lenticule, which serves as the new optical curve for the cornea, is profiled prior to application to the curvature necessary to correct the patient's refractive error. This determination is derived from a database which includes, but is not limited to, factors such as the axial length of the eye, manifest refraction, cycloplegic refraction, manual retinoscopy, automated retinoscopy, and automated refraction. Allowance is also made for the thickness of the epithelium which will recover the lenticule.

With the synthetic lenticule prepared, reference is made to Figures 3 through 11, which illustrate the additional steps of the present invention. The corneal epithelium 22 is normally removed mechanically, as shown in Figure 3, with a chemical solution on a swab or by other suitable means.

Figure 5 illustrates diagrammatically a combination scanning device for mapping the contour of the eye and laser delivery system 44, a preferred system providing energy generated by a pulsed laser, which is used for mapping, for etching a peripheral groove in the cornea, and for reprofiling the lenticule after its application. One suitable laser system is an argon fluoride excimer laser, the energy produced having a wavelength of 193nm. The system is capable of a precisely determined removal of corneal tissue without thermal or mechanical damage to adjacent regions of the tissue. Such a system is discussed in U.S. Patent No. 4,665,913 to L. Esperance, Jr. for a Method For Ophthalmological Surgery. Other suitable laser delivery systems may also be used, such as a 2.9 micron infrared laser system.

The patient's eye is fixed at the limbus 46, to the housing 48 of the system, by a limbal suction ring 50, a vacuum within the ring being created by evacuating the air within the ring through ports 51. Taking into consideration the diameter and the configuration of the peripheral edge 52 of the prepared lenticule 40, the laser delivery system is programmed to etch a shallow peripheral groove 54, extending into or through Bowman's layer 24 and into the stroma 30. A template (not shown) or a specialized lens, such as an axicon lens (not shown) may be used to direct and focus the microprocessor controlled laser output, forming the groove in a peripheral, optically insignificant region of the cornea. Thus, as shown in Figure 6, the groove is formed well outside the visual axis of the patient. In addition to a suitable laser delivery system, mechanical cutting means, such as a trephine, may be used to form the groove provided the mechanical means used includes the required precision to form the groove without damage to adjacent tissue under the control of a skilled surgeon.

With the groove 54 formed, a suitable adhesive means 56 is applied therein to receive and bond

the lenticule to the cornea, as shown in Figure 7. A preferred adhesive is a collagen-based glue so as to be biocompatible with the corneal stroma and with the lenticule. Other suitable securing means may also be used, for example, suturing, with a suitably prepared lenticule, preferably having preformed apertures to receive the sutures, thus preventing asymmetrical tension on the eye or lenticule.

Figure 8 diagrammatically illustrates the lenticule application apparatus 58. The eye is fixed as shown in Figure 5, like elements being defined by like numerals, with suction ring 50 securing the apparatus to the limbus 46 of the eye. The apparatus is similar in use to that shown in Figure 5 as far as attachment to the eye; however, certain features have been added as described hereinbelow. The lenticule 40 is held by a suction ring 60 having a vacuum line 61, the ring 60 being attached to a micromanipulator system. The vacuum line communicates with the posterior surface of the suction ring so as to selectively create a vacuum between the ring and the lenticule. The micromanipulator has a horizontal carriage 62, a vertical carriage 64, and a 360° gimbal 66, thus being capable of movement in any axis as well as translations across these axes. The unit is powered through electrical power lines or cables 67 and is driven by a motor 65 which receives signals from a microprocessor 68. The micromanipulator unit is controlled by the surgeon with conventional remote control means (not shown). After the adhesive means 56 is applied in the groove by a suitable applicator (not shown), the main chamber 69 is evacuated of air through suction ports 70. With a sufficient vacuum obtained, the lenticule 40 is lowered into position on the cornea. The surgeon may utilize fiberoptic viewing ports 72 to assist in alignment of the peripheral edge 52 of the lenticule with the groove 54.

Once the lenticule is in position, as shown in Figure 9, the vacuum in the main chamber is released. Since the mating of the lenticule with the corneal surface occurs under conditions of low pressure, the return of ambient air pressure causes a firm seating of the lenticule to the cornea. This assures good approximation of the posterior surface of the lenticule to the corneal layer during the bonding period of the glue which normally takes several minutes. The glue achieves permanent bonding of the peripheral edge of the lenticule in the groove. The precision etching of the groove by the laser, as dictated by the diameter of the lenticule and the configuration of the peripheral edge 52 thereof, assures that the anterior surface of the edge portion is substantially flush with the outer, adjacent corneal layer, thus providing no mechanical barrier to the epithelial cell layer which then regrows over the lenticule.

After placement of the overlay into position on the cornea, certain pharmacological agents may be applied which enhance and speed the growth of epithelial cells over the lenticule, agents such as fibronectin, epidermal growth factor, and antibiotics. With these agents, epithelial covering will normally be complete within several days, this being illustrated in Figure 11.

After the lenticule is covered with epithelium, it is expected the patient's refractive error will be largely, if not completely, corrected. However, if further refractive adjustments are necessary, a suitable laser delivery system, as previously described and shown in Figure 5, can be used to reprofile the anterior curvature of the lenticule to the desired shape. The data used to determine reprofiling criteria are determined in follow-up examinations and may include the previous data obtained on the patient, corneal topographic mapping, automated and cycloplegic refraction measurements, and any other pertinent data.

Should reprofiling of the lenticule be required at any time after placement of the overlay, the corneal epithelium is removed as previously described, the eye then being as shown in Figure 9. The laser delivery system shown in Figure 5 is set up and the eye is fixed at the limbus 46 as discussed hereinabove. Assuming, for example, that a myopic condition still exists or develops later, the laser is directed to reprofile the surface of the lenticule 40 in the central region thereof, thereby reducing the curvature, this being schematically illustrated in Figure 10. To increase the curvature, the laser ablation would be directed to the peripheral regions of the lenticule (not shown), thus steepening the curve and adjusting for a hyperopic condition. After reprofiling, the epithelium regrows over the lenticule, as shown in Figure 11. Thus, the lenticule's design, including its thickness and composition, allows for laser reprofiling of its anterior surface after attachment to the patient's eye. Such reprofiling allows correction of residual refractive errors. The process thus provides patients with refractive errors an alternative means of correcting their vision without the need for spectacles, contact lenses, or current surgical techniques, and allows for future corrections to be made as needed.

Thus, it is believed apparent to those skilled in the art, the many advantages of the process of applying a synthetic overlay, laser-adjustable, refractive surface over present techniques of refractive surgery including improved safety, predictability, and stability, as well as the option to adjust or remove the overlay.

The safety of the process is evident in that the central optical zone of the patient's cornea is never violated. A shallow peripheral excision is made well outside of the visual axis. In contrast, photorefrac-

tive keratectomy involves directly ablating corneal tissue within the optical zone. Any malfunction of the laser delivery system, debris on the cornea, or unintended ocular motion during ablation will result in severe optical effects for the patient.

Compared with current techniques, no significant structural weakening of the cornea occurs with the method described with this invention. Radial keratotomy, on the other hand, significantly weakens the cornea by making multiple, near full thickness incisions. Photorefractive keratectomy will remove a variable amount of anterior corneal tissue depending on the required refractive change. For example, correcting a 10 diopter refractive error over a six mm optical zone will require removing nearly 20% of the corneal thickness, a very significant amount.

Another safety advantage to the synthetic overlay technique is the avoidance of direct irradiation of the optical axis of the eye with far ultraviolet laser energy. Although current evidence suggests the 193 nm excimer laser is initially effective for corneal surgery, long term hazards such as delayed corneal scarring are minimized by confining laser ablation to a small peripheral region of the cornea which is optically insignificant to the patient.

A significant improvement in predictability in refractive outcome is provided by the present technique. Since there is no significant structural weakening of the cornea, variables induced by curvature changes of the patient's cornea will not be encountered after the procedure, the actual result closely approximating, if not matching, the anticipated change.

Once the lenticule covers with epithelium, the refractive result remains stable over time. Since the overlay is composed of a material which prevents degradation by cells or cellular agents, no refractive shift caused by collagen deposition or removal is encountered as is seen in photorefractive keratectomy.

A further, significantly unique feature of the synthetic overlay process described herein is the ability to adjust the refractive power of the lenticule after it is placed on the cornea. Unlike procedures such as radial keratotomy or epikeratophakia which are not adjustable, the overlay can be reprofiled while in place on the corneal surface if a new refractive power is needed. Although photorefractive keratectomy procedures could be repeated on patients who did not achieve their desired correction, each treatment would irreversibly remove more of the patient's central corneal tissue.

The techniques described in this invention provide a mechanism to apply and secure a synthetic lenticule to the surface of the eye while avoiding the undesirable mechanical distorting forces associated with present techniques of corneal bed prep-

aration and suturing. Achieving a precise fit of the lenticule to the host bed with a tolerance of only a few microns is not possible with present corneal trephination devices or mechanical cutting instruments. These instruments typically cause large areas of disrupted and distorted tissue and are totally incapable of achieving the precision necessary for lenticule attachment. Grooving the cornea with the delivery optics described in this invention represents a significant advancement over present techniques in preparing the cornea for the lenticule.

Similarly, attachment of the lenticule to the cornea by conventional suturing methods is not acceptable for the purpose of this invention. Regardless of the skill of the surgeon, suturing will always impart asymmetric tension between the host cornea and lenticule. The method of attachment described in this invention, including the use of collagen compatible adhesive and a vacuum system to create high surface tension between the cornea and the lenticule, represents a significant advance over presently available methods.

Finally, the method described herein is reversible. Unlike radial keratotomy or photorefractive keratectomy which are essentially irreversible procedures, the synthetic lenticule may be removed if unforeseen problems develop. Thus, a malfunction in the laser reprofiling delivery system as described above may render the synthetic lenticule optically unacceptable, but would leave the patient's central cornea completely intact, and a substitute lenticule can easily be applied.

While an embodiment of an apparatus and process for application and adjustable reprofiling of synthetic lenticules for vision correction and modifications thereof have been shown and described in detail herein, various additional modifications may be made without departing from the scope of the present invention.

Claims

1. A process for application and adjustable reprofiling of a synthetic lenticule to the cornea of the human eye for correcting vision, comprising the steps of:

- a) preparing a topographic map of the anterior surface of the cornea;
- b) profiling the posterior surface of a synthetic lenticule to closely match the anterior surface of the cornea, said lenticule being constructed so as to correct the patient's particular refractive error;
- c) removing the outer epithelial cell layer from the anterior surface of the cornea;
- d) forming a shallow peripheral groove in the cornea, outside the visual axis of the eye;
- e) applying adhesive means in said groove;

f) placing the peripheral edge of said lenticule in said groove whereby said lenticule is disposed over the cornea; and

5 g) ablating by laser predetermined portions of said lenticule for refining its refractive power whereby the outer epithelial layer regrows over said lenticule.

10 2. A process as defined in claim 1 and including the additional step of applying pharmacological agents over said applied lenticule for enhancing epithelial growth thereover.

15 3. A process as defined in Claim 1 and including the additional steps of removing the regrown corneal epithelial layer and reprofiling said lenticule with a laser for further refining the refractive power of the lenticule.

20 4. A process as defined in Claim 3 and including the additional step of applying pharmacological agents over said reprofiled lenticule for enhancing epithelial growth thereover.

25 5. A process as defined in Claim 1 and including the additional step of performing said step (f) under vacuum conditions.

6. A process as defined in Claim 1 wherein said groove is formed by a laser.

7. A process as defined in Claim 1 wherein said groove is formed by a mechanical cutting means.

30 8. A process for application and adjustable reprofiling of a synthetic lenticule to the cornea of the human eye for correcting vision, comprising the steps of:

35 a) removing the outer epithelial cell layer from the anterior corneal surface layer;

b) forming a shallow, peripheral groove in the exposed cornea, outside of the visual axis of the eye;

40 c) securing the prepared lenticule over the cornea, disposing the peripheral edge thereof in said groove where it is fastened by a suitable securing means.

45 9. A process as defined in Claim 8 and including the additional step of selectively ablating by laser predetermined portions of said lenticule for refining the refractive power thereof.

10. A process as defined in Claim 8 in which said securing means includes an adhesive.

50 11. A process as defined in Claim 8 in which said step (c) is performed by suturing said lenticule to the cornea.

55 12. A process as defined in Claim 8 and including the additional steps of preparing a topographical map of the anterior surface of the cornea and profiling the posterior surface of said lenticule to closely approximate said anterior surface of the cornea.

13. A process as defined in Claim 8 and including the additional step of applying pharmacological agents over said lenticule for enhancing epithelial growth thereover.

14. A process as defined in Claim 8 and including the additional step of performing step (c) under vacuum conditions.

15. A process for selectively reprofiling a synthetic lenticule which has been secured over the cornea of a human eye for refining the refractive power of the lenticule, comprising the steps of

- a) removing the epithelial layer from the anterior surface of the lenticule; and
- b) ablating predetermined portions of the lenticule with a laser for refining the refractive power of the lenticule.

16. A process as defined in Claim 15 and including the additional step of applying pharmacological agents over the reprofiled lenticule for enhancing regrowth of the epithelial layer thereover.

17. An apparatus for placing a prepared synthetic lenticule over the cornea of a human eye for correcting a patient's refractive error, the cornea having a peripheral groove etched therein with an adhesive means disposed therein for receiving the peripheral edge of said lenticule, said apparatus comprising a chamber having means at the lower edge thereof for securing said chamber to the limbal region of the eye for preventing substantial movement of the eye with relation to said chamber, a micromanipulation system disposed in said chamber, including a horizontal carriage means, a vertical carriage means, and a gimbal means operatively associated together for effecting movement along any axis and in translations across said axes, a motor and power source for selectively driving said micromanipulation system, a suction ring means secured to said gimbal means for holding said lenticule prior to application thereof, and control means operable by the physician for manipulating said lenticule.

18. An apparatus as defined in Claim 17 in which said apparatus further includes means for sealing said chamber and vacuum means for evacuating the air from said chamber.

19. An apparatus as defined in Claim 17 in which said suction ring means includes a vacuum means operatively associated therewith for creating a vacuum between said suction ring means and said lenticule for selectively holding said lenticule.

20. A process for application and adjustable reprofiling of a synthetic lenticule to the cornea of the human eye for correcting vision, comprising the steps of:

- a) removing the outer epithelial cell layer from the anterior corneal surface layer;

b) ablating by laser forming shallow, peripheral groove in the exposed cornea, outside of the visual axis of the eye;

5 c) applying an adhesive means in said groove; and

d) placing the prepared lenticule over the cornea, disposing the peripheral edge thereof in said groove where it is secured by said adhesive means.

10 21. A process as defined in Claim 20 and including the additional step of selectively ablating by laser predetermined portions of said lenticule for refining the refractive power thereof.

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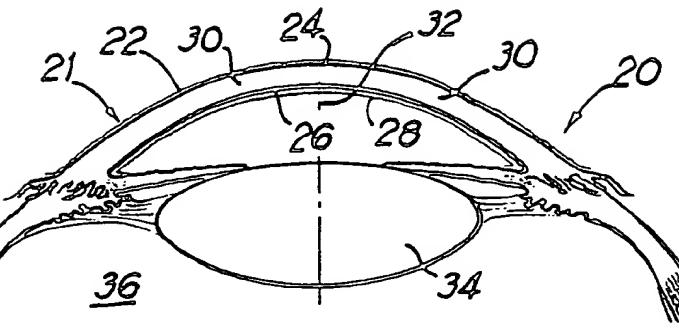


FIG 1

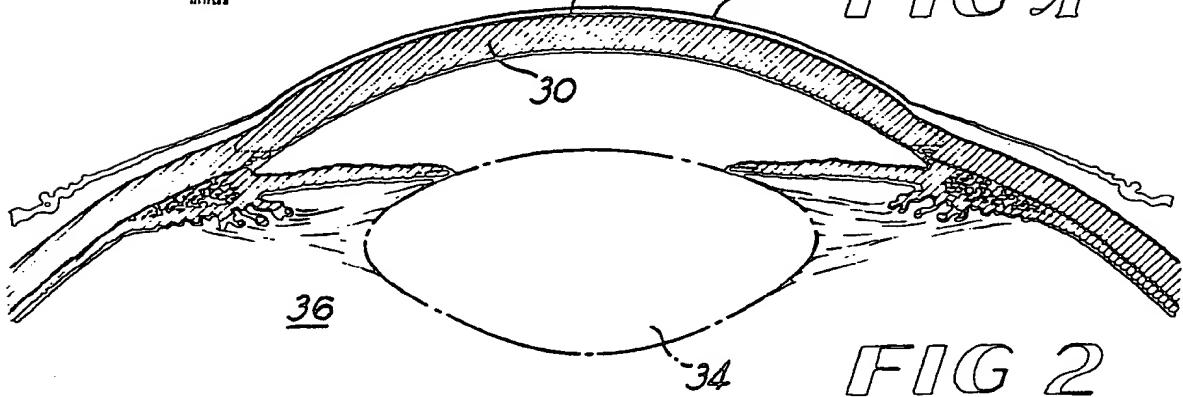


FIG 2

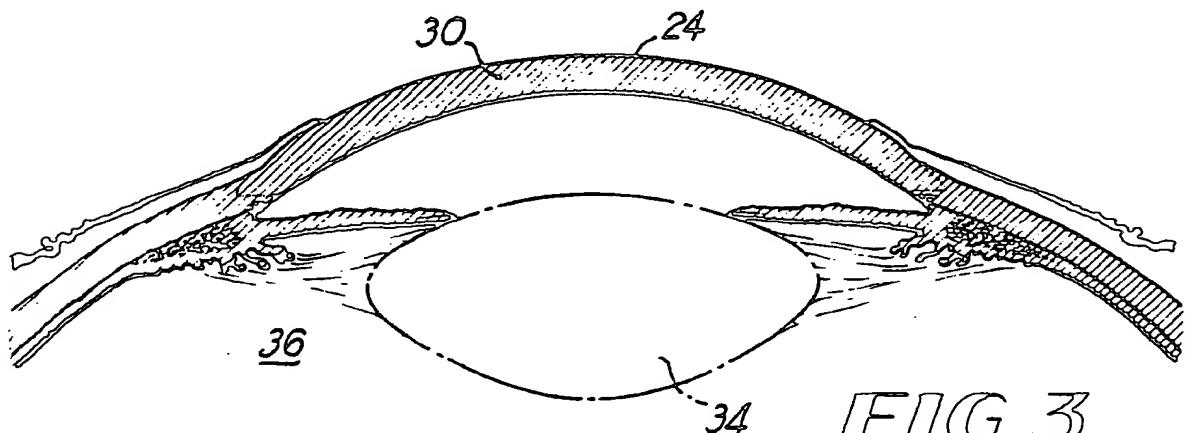


FIG 3

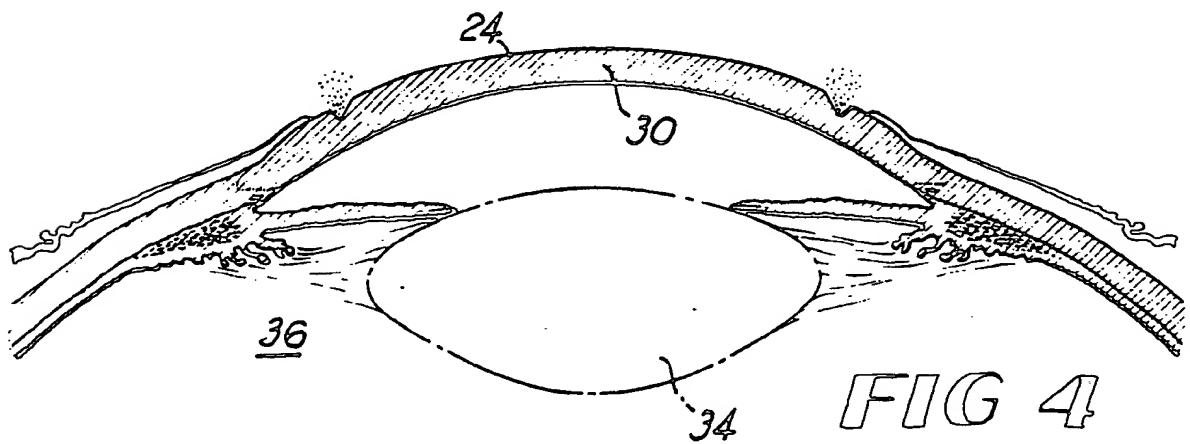
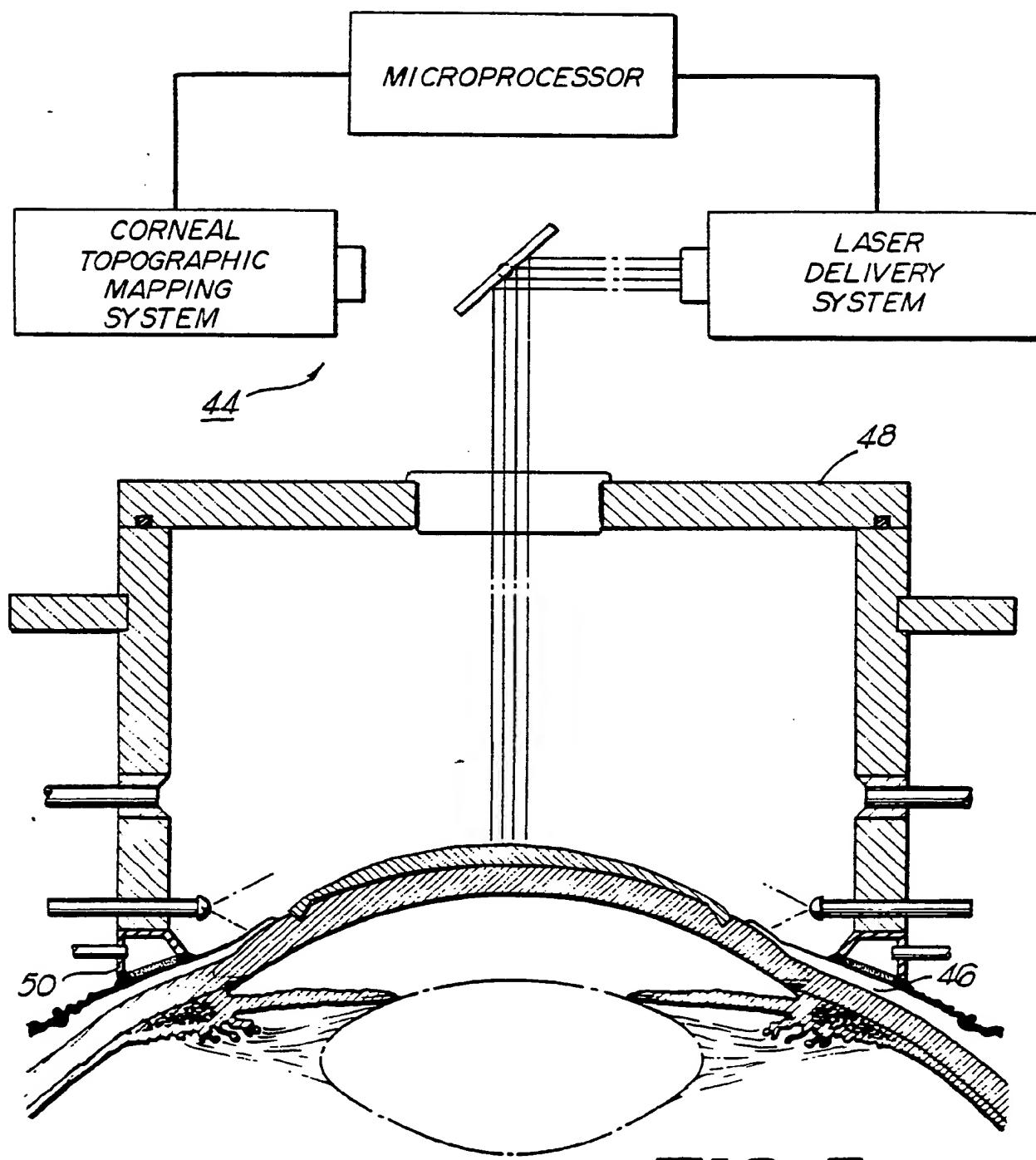
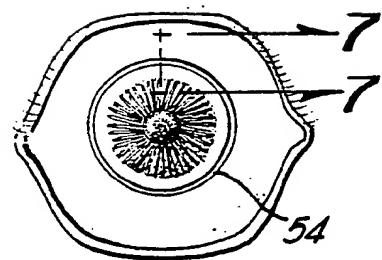
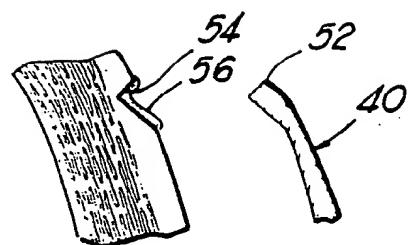
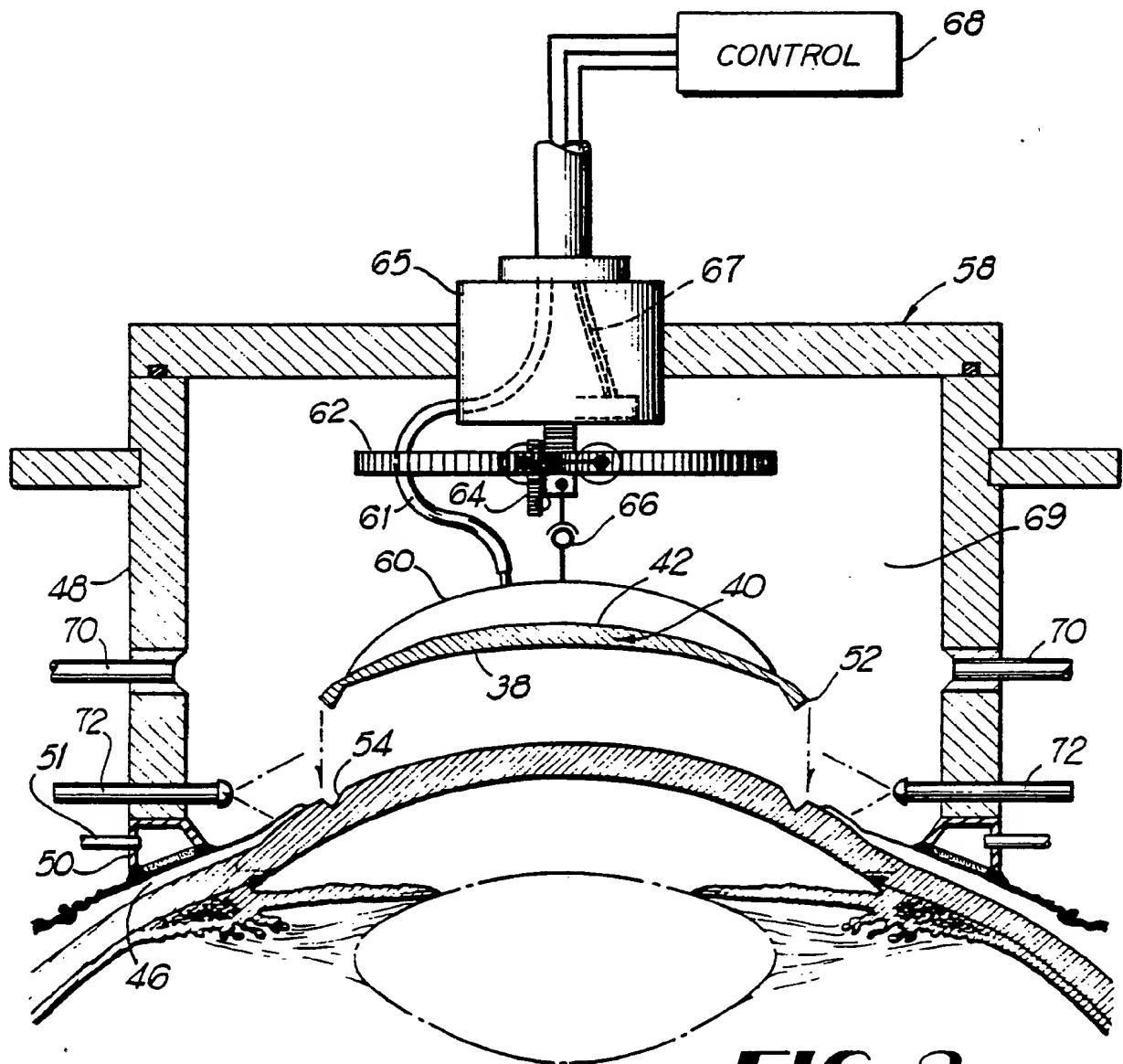
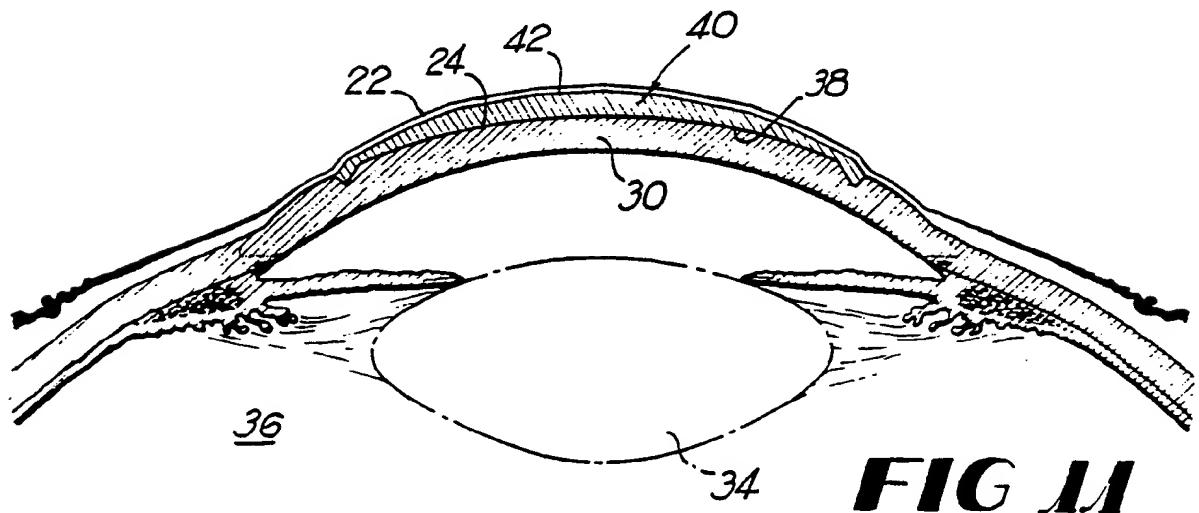
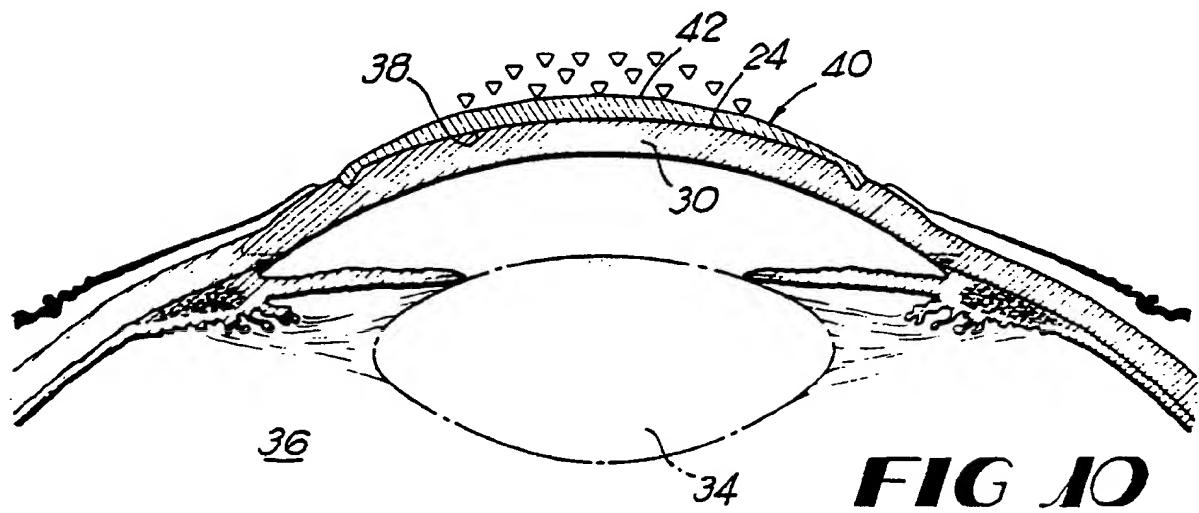
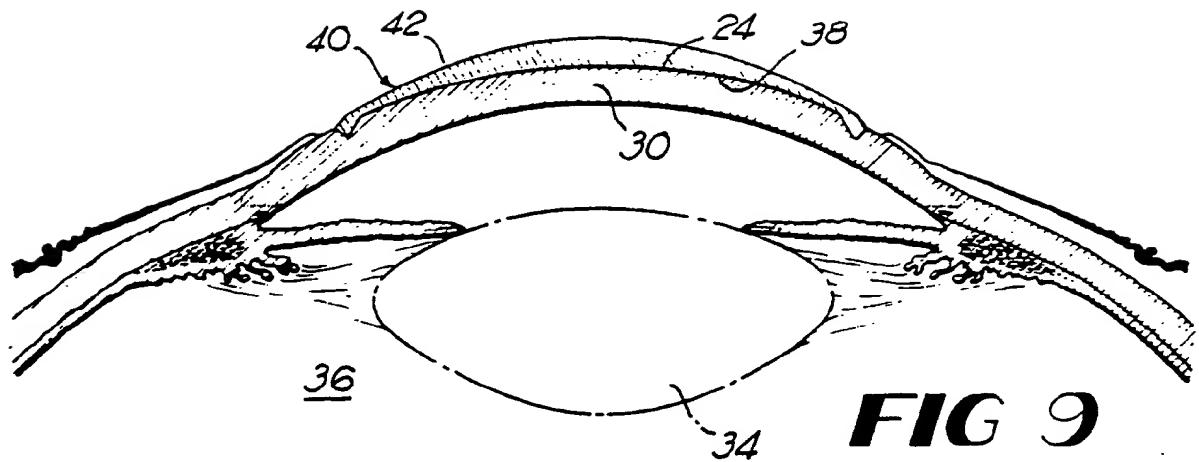


FIG 4

**FIG 5**

**FIG 6****FIG 7****FIG 8**





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Application number

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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	EP-A-0 208 950 (GRÜNDLER) * Claims 1,3,4,6,15,19; figures 1,5,6 *	17-19	A 61 F 9/00 A 61 F 2/14
A,D	-- US-A-4 665 913- (L'ESEPERANCE) * Column 3, lines 42-52; figure 2 *	17	
A	-- DE-B-1 912 421 (HENNING) * Claim 1; figure 6 *	19	
P,A	-- EP-A-0 303 174 (GRIESHABER & CO) * Column 4, lines 35-45; figures 1, 2 *	18	
A	-- WO-A-87 01 930 (KERN) * Whole document*-=====		
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.</p> <p>Claims searched completely: 17-19</p> <p>Claims searched incompletely:</p> <p>Claims not searched: 1-16; 20, 21</p> <p>Reason for the limitation of the search:</p> <p>Method for treatment of the human or animal body by surgery or therapy (see art. 52(4) of the European Patent Convention).</p>			
Place of search	Date of completion of the search	Examiner	
The Hague	06-06-1989	NICE	
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